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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,693	02/08/2000	Insu Lee	00120/P-4858	1622

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EXAMINER
WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/499,693	LEE ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,8 and 19-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,8 and 19-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1, 6, 8 and 19-45 are pending. The Amendment received March 28, 2002, cancelled claims 2, 5, 7, 9-18, amended claims 1, 6, 8, 19, 21, and added claims 23-45.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27, 35, 39 and 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Rapeseed oil was never disclosed in the original specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6, 8, and 19-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The terms "18:2" and "18-3" in claims 1, 6, 8, 19, 21 are vague and indefinite, as it is not clear if the ":" and the "-" are synonymous or if they denote different relationships.

(ii) Claims 19-25 recites the limitation ""in claim 2". There is insufficient antecedent basis for this limitation in the claim, as claim 2 has been cancelled.

(iii) The phrase "such that the weight ratio of the daily supply of said linoleic fatty acid to said alpha-linolenic fatty acid in said animal is 0.05-2" in claims 21 (lines 2-4) is vague and indefinite, as it is confusing. What is a ratio of a daily supply? What is this phrase conveying?

(iv) The term "foodstuff" in claims 23-25 and 42-45 is vague and indefinite, as it is not clear what this term means. The specification does not further define this term and one of ordinary skill in the art would not be apprised of its meaning.

(v) Claims 24 and 25 are vague and indefinite, as they are confusing. How can claim 24 depend on claim 23 and have the foodstuff of claim 19, when claim 23 depends on the composition of claim 2? Synonymous reasoning is applied to claim 25.

(vi) Claims 26-45 are rejected as vague and indefinite, as they are confusing. What does it mean that these compositions comprise flaxseed oil, wherein the compositions comprise linoleic fatty acid and linolenic fatty acid? Is a composition comprising flaxseed oil, linoleic fatty acid, and linolenic fatty acid being claimed? Is something else being claimed?

(vii) The term "edible oil" in claim 34 is vague and indefinite, as it is unclear. What oils are encompassed by term "edible". What differentiates an "edible oil" from a "non-edible oil". The specification does not define this term and one of ordinary skill in the art would not be apprised of its meaning.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 211502.

EP '502 disclose administration of linoleic and alpha linolenic acid for the treatment of premenstrual syndrome. The linoleic acid and alpha linolenic acid may be administered with or without a suitable carrier or diluent. See abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 8, 19-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Yehuda (5,416,114) in view of Igarashi (6,159,507).

Yehuda teaches a physiologically active and nutritional composition consisting of 13-27.5% linolenic acid and 87-72.5% of linoleic acid. The compositions can be in the form of a capsule. The reference lacks preferred ratios, and explicit teachings of (n-6, 18:2) and (n-3, 18:3). See Col. 4, line 61-Col. 6, line 48; Col. 17, line 1-Col. 20, line 55.

Igarashi teaches a method of modifying the balance of omega unsaturated fatty acids, wherein the omega fatty acids are omega-3 and omega-6 fatty acids. It is disclosed that these two series of unsaturated fatty acids mutually have a potent effect on the physiological action of the other, as well as that both of these series of fatty acids cannot be biosynthesized in the body. A preferred balance of omega-6 to omega-3 fatty acids is 1 to 5 or 6. Alpha-linolenic acid is

disclosed as a preferred omega-3 fatty acid, and linoleic acid is disclosed as a preferred omega-6 fatty acid. The compositions are disclosed in the form of a capsule and methods of making food from the omega-3/omega-6 compositions are disclosed. See Col. 1, line 16-Col. 2, line 65; Col. 5, line 64-Col. 6, line 41; Col. 7, lines 1-8; Col. 7, lines 55-Col. 9, line 7; Col. 9, line 40-Col. 10, line 50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the linolenic acid and linoleic acid of Yehuda as (n-6, 18:2) and (n-3, 18:3), as disclosed by Igarashi because a)Yehuda and Igarashi both teach linolenic and linoleic acid compositions for use in nutritional supplements/food, and; b) Igarashi teaches that combining alpha linolenic acid (n-3, 18:3) with linoleic acid (n-6, 18:2) results in a potent in vivo effect of one fatty acid on the physiological action of the other, and further teaches that such a combination has lipid lowering effects and decreased mortality rates due to arteriosclerotic diseases; thus, since Yehuda and Igarashi utilize linoleic and linolenic acid for nutritional supplements, and Igarashi teaches the benefits of the combination of linoleic acid (n-6, 18:2) and alpha linolenic acid (n-3, 18:3), the teaching of linoleic acid as (n-6, 18:2) and linolenic acid as (n-3, 18:3) in the invention of Yehuda, for nutritional purposes, would be within the skill of one in the art.

Claims 1, 6, 8, 19-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Harumi et al. (JP 61-85143) in view of Igarashi (6,159,507).

Harumi et al. teach an edible fat and oil compositions comprising perilla seed oil and linseed oil, wherein linolenic acid and linoleic acid are in good balance. The reference lacks preferred ratios and explicit teaches of (n-6, 18:2) and (n-3, 18:3). See abstract.

Igarashi is applied as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the linolenic acid and linoleic acid of Harumi as (n-6, 18:2) and (n-3, 18:3), as disclosed by Igarashi because a) Harumi and Igarashi both teach linolenic and linoleic acid compositions for use in nutritional supplements/food, and; b) Igarashi teaches that combining alpha linolenic acid (n-3, 18:3) with linoleic acid (n-6, 18:2) results in a potent in vivo effect of one fatty acid on the physiological action of the other, and further teaches that such a combination has lipid lowering effects and decreased mortality rates due to arteriosclerotic diseases; thus, since Harumi and Igarashi utilize linoleic and linolenic acid for nutritional supplements, and Igarashi teaches the benefits of the combination of linoleic acid (n-6, 18:2) and alpha linolenic acid (n-3, 18:3), teaching linoleic acid as (n-6, 18:2) and linolenic acid as (n-3, 18:3) in the invention of Harumi, for nutritional purposes, would be within the skill of one in the art.

Unexpected Results

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the data in Figures 1-4 are not commensurate in scope with the independent claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
May 1, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
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